Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria™ for pretreatment staging of invasive transitional cell carcinoma of the bladder.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Urologic Imaging. Pretreatment staging of invasive transitional cell carcinoma of the bladder. Reston (VA): American College of Radiology (ACR); 2001. 6 p. (ACR appropriateness criteria). [39 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Invasive transitional cell carcinoma of the bladder (TCCB)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Oncology
Radiation Oncology
Radiology
Urology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of radiologic examinations for pretreatment staging of invasive transitional cell carcinoma of the bladder (TCCB)

TARGET POPULATION

Patients with invasive transitional cell carcinoma of the bladder (TCCB)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Excretory urography (intravenous pyelogram [IVP])
2. Chest x-ray (CXR)
3. Magnetic resonance imaging (MRI): pelvis
4. Computed tomography (CT): pelvis/abdomen
5. Computed tomography: chest
6. Nuclear medicine: bone scan
7. Ultrasound (US): transabdominal bladder
8. Magnetic resonance imaging: abdomen
9. Ultrasound: transrectal bladder
10. Metastatic skeletal survey

Note: Only invasive tumors will be considered. The imaging work-up begins after the tumor has been identified cystoscopically and has been proven by biopsy.

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in the pretreatment staging of invasive transitional cell carcinoma of the bladder (TCCB)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Clinical Condition: Pretreatment Staging of Invasive Bladder Cancer

Radiologic Exam Procedure	Appropriateness Rating	Comments
IVP	9	Up to 6% of patients with TCCB have synchronous upper tract lesions.
Chest x-ray	9	Effective screen of site of most common hematogenous metastasis.
MRI: pelvis	8	
CT: pelvis/abdomen	6	
CT: chest	3	Probably not indicated unless chest x-ray is suspicious.
Nuclear medicine: bone scan	3	Probably not indicated unless bone pain is present.
Ultrasound: transabdominal bladder	3	Limited visualization beyond the bladder wall.
MRI: abdomen	3	Probably not indicated unless CT is inconclusive.
Ultrasound: transrectal bladder	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
Metastatic skeletal survey	1	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1=Least appropriate 9=Most appropriate		

Abbreviations: IVP, excretory urography/intravenous pyelogram; TCCB, transitional cell carcinoma of the bladder; MRI, magnetic resonance imaging; CT, computed tomography

The average age of patients with transitional cell carcinoma of the bladder (TCCB) in the United States is 65 at diagnosis with a 4 to 1 male to female ratio. In 2001, it was estimated that 54,300 new cases of bladder cancer will be diagnosed and 12,400 will die of the disease. Almost 80% of patients with TCCB present with hematuria, which is either gross or microscopic and is usually painless and intermittent. Transitional cell carcinoma of the bladder spreads by local extension through the basement membrane into the muscular layer, then to the perivesical fat. Progressive extension into the muscular layer allows vascular and lymphatic invasion and more distant spread. The most common sites of hematogenous spread are lung, bone, liver, and brain. Superficial lesions do not metastasize until they invade deeply and may remain indolent for many years. Up to 85% of TCCB is superficial at presentation. Only invasive tumors will be considered. The imaging work-up begins after the tumor has been identified cystoscopically and has been proven by biopsy.

TCCB is staged by its extension at presentation and graded I-IV according to microscopic criteria of aggressiveness. The standard staging systems for bladder cancer (see Table 1 in the original guideline document) are the Jewett Strong Marshall (JSM) classification and the Tumor Node Metastasis (TNM). In the classic Jewett Strong Marshall staging system, A is divided from B by the lamina propria, B is divided into superficial versus deep infiltration of the muscularis, B from C by the serosa of the bladder, and D is characterized by involvement of regional then distant nodes or other organ involvement. The division of Stage B into superficial and deep is based on Jewett's observation of an 80% 5-year survival rate of patients with B1 lesions compared with 8% for patients with B2 lesions in a small series. The Tumor Node Metastasis system encompasses the status of the primary tumor (T), the lymph nodes (N), and any metastasis (M).

Tumor grade relates directly to depth of invasion but inversely to curability, so that the 5-year survival rate of patients with grade III and IV superficial tumors is only half that of patients with low-grade I and II superficial tumors (37% versus 71%). Patients with invasive tumors with no nodal involvement have a 5-year survival of 28% and those with nodal involvement have a 5-year survival of 11%.

Treatment ranges from cystoscopic local excision or segmental bladder resection with pelvic lymphadenectomy for early tumors to irradiation, chemotherapy, and/or radical extirpation for deep invasion. Cystectomy and conduit with pelvic

lymphadenectomy are usually not performed on those with known extension beyond the bladder.

Since clinical staging by cystoscopy and bimanual examination under anesthesia is inaccurate in more than 50% of patients, imaging is vital to the proper treatment of these patients. The principal task is to identify extravesical spread. Unfortunately, none of the imaging modalities can identify microscopic spread to muscle layer, perivesical fat, lymph nodes, or other organs.

Cystography, pelvic angiography, lymphangiography (LAG) with or without percutaneous fine-needle aspiration (FNA) biopsy, and plain-film whole-lung laminography are no longer routinely used in staging TCCB since the advent of cross-sectional imaging.

Plain-Film Skeletal Survey

Because plain-film skeletal survey sensitivity is so low, in the range of 17% to 60%, it is no longer used. Plain-film exam is only useful at a site of increased activity on radionuclide bone scan or local bone pain.

Excretory Urography

Excretory urography (intravenous pyelogram [IVP]) remains the best screen for upper tract disease and the most sensitive in detecting small urothelial lesions. Although only 60% of known bladder tumors are visualized by IVP, obstruction of a ureteral orifice at the level of the ureterovesical junction, if stone is excluded, is usually due to invasive bladder tumor. Any degree of ureteric obstruction is significantly associated with both decreased overall survival and decreased tumor-free interval.

Chest X-ray and Computed Tomography

All patients with invasive TCCB need pulmonary evaluation. The chest x-ray (CXR) is an effective, inexpensive low-morbidity screen. Patients with equivocal chest x-ray and those thought to be at high risk should have chest computed tomography (CT).

Radionuclide Bone Scan

Radionuclide skeletal scintigraphy has a sensitivity ranging from 69% to 100% but is highly nonspecific. Solitary bone lesions in patients with underlying primary malignancies are due to metastases in only 55% of cases. The incidence of bone metastases in bladder cancer patients increases with tumor stage at time of diagnosis, from 5% of patients with early-stage invasive tumors to 15% of patients with locally advanced disease. Bone scanning may be limited to patients with bone pain and/or elevated levels of serum alkaline phosphatase. Further evaluation with plain-films and/or magnetic resonance imaging (MRI) can be helpful, and, if necessary, guided needle biopsy can be definitive.

Radionuclide Liver Scan

Although approximately 30% of patients dying of bladder cancer have liver metastases at autopsy, liver metastases at initial presentation are rare. Since abdominal CT has now replaced radionuclide evaluation of the liver, abdominal CT could be reserved for patients with abnormal liver function tests, hepatomegaly, or jaundice. Guided-needle biopsy can provide histologic material from any lesion found.

Ultrasound: Transabdominal, Transrectal, and Transurethral

The distended bladder is a superb acoustic window. Size and location of the tumor affect detectability with ultrasound (US). Lesions smaller than 0.5 cm that are flat and/or near the bladder neck can be easily missed. Nevertheless, detection rates of over 95% are reported. Ultrasound is limited in visualization beyond the bladder wall and cannot detect nodal enlargement. The ultrasound cannot differentiate wall edema, prominent mural folds, postoperative changes, blood clots, or benign masses. Color Doppler with transrectal ultrasound (TRUS) adds nothing to evaluation of stage or grade.

TRUS is excellent for evaluating prostate and seminal vesicles. Transurethral ultrasound (TUUS) is more sensitive than transabdominal ultrasound (TAUS) and TRUS and more accurate in staging depth of wall involvement but is not widely available. Transurethral ultrasound provides local staging information with 62% to 100% accuracy, highest for superficial tumors. Transurethral ultrasound can also detect tumors in diverticula and monitor distention of the bladder wall and transurethral resection of tumor. Transurethral ultrasound staging is unreliable for large tumors (>3 cm) and tumors with calcifications, largely because of acoustic shadowing. It is poor (70%) for evaluation of extravesical spread.

With progression from TAUS to TRUS to TUUS, the diagnostic accuracy of ultrasound has improved.

Computed Tomography of the Pelvis and Abdomen

The primary contribution of CT is distinguishing tumors that are organ confined from those with extravesical extension. It demonstrates bulky thickening of the bladder wall, perivesical extension, lymph node enlargement, and distant metastases very well. Identification of the primary lesion can be difficult in the areas of the bladder neck and dome. The CT cannot distinguish inflammatory postoperative or postradiation edema or fibrosis from tumor and cannot assess depth of invasion of the bladder wall.

Magnetic Resonance Imaging

MRI is superior to CT in demonstrating the lower pelvic anatomy. There is striking inherent contrast between the bright perivesical fat and the intermediate-signal-intensity bladder wall on T1-weighted images. Multiplanar imaging and gadolinium enhancement improve visualization of tumors on T1-weighted images. Fat enhancement techniques can help identify perivesical extension. Deep muscle invasion presents as disruption of the low-signal-intensity bladder wall by tumor, which usually is of higher signal intensity. After intravenous gadolinium chelates, TCCB shows earlier and greater enhancement than normal bladder or nonmalignant tissue.

CT versus MRI

Both CT and MRI rely on enlargement of lymph nodes as a criterion for metastasis. Lymph node metastasis in patients with superficial tumors (less than T3) is rare, but if deep muscle layers are involved ($T3_a$) or if extravesical invasion is seen, the incidence of lymph node metastasis rises to 20% to 30% and 50% to 60%, respectively. If a lymph node is considered to contain metastasis, a FNA biopsy should be considered. Both CT and MRI are considered similar in their ability to detect nodal enlargement.

Recommendations

IVP and CXR are necessary. Cystography, angiography, LAG with or without FNA biopsy and plain-film whole-lung laminography are not indicated. Radionuclide bone scan is not indicated without bone pain and/or elevated serum alkaline phosphatase levels. Plain-film skeletal survey is seldom productive, and plain-films can be limited to sites of increased uptake and/or bone pain. The literature shows that radionuclide liver scan is not helpful without hepatomegaly, jaundice, or elevated liver function tests. Since abdominal CT has replaced this study, the same restrictions could apply. However, it is simple to combine examination of the abdomen with the pelvis on CT or MRI. Chest CT can be limited to those with equivocal CXR. US is useful for local tumor (T) staging; TUUS is the most effective in this regard. MRI is preferred over CT for local staging and is equivalent in the assessment of regional lymph nodes. CT of the brain is needed only if neurological symptoms are present. Early reports on use of ^{111}Indium labeled anti MUCI Mucin Monoclonal Antibody C595 has shown potential to improve chemical staging; however, use of positron emission tomography (PET) scan to date has not proved to be beneficial in comparison to conventional methods.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate evaluation of radiologic exam procedures for pretreatment staging of invasive transitional cell carcinoma of the bladder (TCCB)

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other coexistent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR), Expert Panel on Urologic Imaging. Pretreatment staging of invasive transitional cell carcinoma of the bladder. Reston (VA): American College of Radiology (ACR); 2001. 6 p. (ACR appropriateness criteria). [39 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2001)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria™.

GUIDELINE COMMITTEE

ACR Appropriateness Criteria™ Committee, Expert Panel on Urologic Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It updates a previous version: Bigongiari LR, Amis ES, Bluth EI, Bush WH, Choyke PL, Fritzsche P, Holder L, Newhouse JH, Sandler CM, Segal AJ, Resnick MI, Rutsky EA. Pretreatment staging of invasive transitional cell carcinoma of the bladder. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):697-702.

All Appropriateness Criteria™ topics are reviewed annually and updated as appropriate.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Portable Digital Assistant (PDA): ACR Appropriateness Criteria™ - Anytime, Anywhere (PDA version) is available from the ACR Web site.

Print copies: Available from the American College of Radiology, Department of Quality & Safety, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- American College of Radiology ACR Appropriateness Criteria™ introduction. Reston (VA): American College of Radiology; 6 p. Available in Portable Document Format (PDF) from the ACR Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer as of June 29, 2001. This summary was updated by ECRI on September 8, 2004. The updated information was verified by the guideline developer on October 8, 2004.

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